UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte MARK S. ABAD,
ROBERT E. BUEHLER,
JOSEPH R. BYRUM,
BRIAN E. COOMBS,
GREGORY R. HECK,
THOMAS J. LA ROSA,
DONALD E. NELSON,
HRIDAYABHIRANJAN SHUKLA, and
MICHAEL D. THOMPSON

Appeal 2006-3376
Application 09/615,606
Technology Center 1600

ON BRIEF

Before SCHEINER, GRIMES, and LEBOVITZ, *Administrative Patent Judges*.

LEBOVITZ, *Administrative Patent Judge*.

DECISION ON APPEAL

Claims 1 and 8-13, all the pending claims, are on appeal. Br. 2. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

STATEMENT OF THE CASE

This appeal involves claims to a substantially purified nucleic acid molecule having the nucleic sequence of SEQ ID NO:2. The nucleic acid was randomly selected from a soybean cDNA library. Specification 1: 5-15; 104: 20 to 119: 18 (Examples). It is also known as an "expressed sequence tag" or an "EST." *Id.* at 1: 13. SEQ ID NO:2 is one of 91,663 ESTs described in the instant application. *Id.* at 11. The ESTs described in the application encode proteins or protein fragments and represent mRNAs which are expressed in soybean cells. *Id.* at 1.

There are two rejections on appeal:

1) Claims 1 and 8-13 stand rejected under 35 U.S.C. § 101 as lacking utility. Answer 3. These claims are also rejected under § 112, first paragraph as lacking enablement because one skilled in the art would not know how to use an invention which lacks utility. *Id.* at 5. If a claim fails to meet the utility requirement of 35 U.S.C. § 101 because it is not useful, then it necessarily fails to meet the how-to-use aspect of the enablement requirement of 35 U.S.C. § 112, first paragraph. *In re Fouche*, 439 F.2d 1237, 1243, 169 USPQ 429, 434 (CCPA 1971) (If "compositions are in fact useless, appellant's specification cannot have taught how to use them."); Manual of Patent Examination Procedures (MPEP) 2164.07 (Edition 8, August 2001; revised August 2006).

Although Appellants assert that claims 8, 9, and 10-13 are separately patentable (Br. 10), they rely on the same arguments presented for claim 1. Consequently, for the purpose of deciding this rejection, we select claim 1 as representative. *See* 37 C.F.R. § 41.37(c)(1)(vii). Claim 1 reads as follows:

> 1. A substantially purified nucleic acid molecule that encodes a soybean protein or fragment thereof comprising a nucleic acid sequence of SEQ ID NO: 2.

2) Claims 1, 8, and 10-13 stand rejected under 35 U.S.C. § 112, first paragraph, as lacking written description (*id.* at 6).

We select claims 1 (see above), 8, and 10 as representative:

> 8. A substantially purified nucleic acid molecule comprising a nucleic acid sequence of SEQ ID NO: 2 or complement thereof.
>
> 10. A substantially purified nucleic acid molecule comprising a nucleic acid sequence having between 100% and 90% sequence identity with a nucleic acid sequence of SEQ ID NO: 2 or complement thereof.

ISSUES

Utility under 35 U.S.C. § 101

The Examiner contends that the claimed substantially purified nucleic acid molecule lacks patentable utility under 35 U.S.C. § 101. Answer 3. The Examiner asserts that the general uses of nucleic acids which are set forth in the specification, including "acquiring genes, identifying polymorphisms, determining plant traits, and DNA mapping" are "not considered to be specific and substantial in view of the limited information provided in the specification." *Id.* at 4.

Appellants contend that the disclosed utilities, including using the nucleic acids as probes and primers, and to identify polymorphisms, satisfy the utility requirement under 35 U.S.C. § 101 because they provide an identifiable benefit. Br. 4.

The issue in this appeal is whether the asserted utilities for the claimed nucleic acid molecules satisfy the utility requirement under 35 U.S.C. § 101.

Written description under 35 U.S.C. § 112, first paragraph

The Examiner contends that there is insufficient written description of the claimed nucleic acid molecule comprising SEQ ID NO:2, and of molecules having sequence identity to it, because the claims embrace a genus of molecules which are not described in the specification. Answer 6-7.

Appellants contend that SEQ ID NO:2, which is disclosed in the specification and recited in the claims, is sufficient to describe the claimed invention. Br. 17.

The issue in this appeal is whether Appellants' disclosure of SEQ ID NO:2 is adequate to satisfy the written description requirement under 35 U.S.C. § 112, first paragraph, for claims to nucleic acid molecules which comprise SEQ ID NO:2 or which have 90% to 100% sequence identity to it.

FACTS

1. Claim 1 is drawn to "a substantially purified nucleic acid molecule that encodes a soybean protein or fragment thereof" comprising SEQ ID NO:2. Claims 8 and 10 are also directed to "a substantially purified nucleic acid molecule," but do not recite that it encodes a protein. All the pending claims refer to SEQ ID NO:2.

2. SEQ ID NO:2 is a definite and ordered sequence of nucleotides.

3. The nucleic acid sequence of SEQ ID NO:2 is obtained by sequencing a cDNA isolated from a soybean cDNA library. Specification 1: 13 to 4: 22; 104: 20 to 119: 18 (Examples); Br. 18.

4. The specification does not disclose an open reading frame for SEQ ID NO: 2 nor information about the protein it encodes. Answer 4.

5. The specification discloses a number of uses for the claimed nucleic acid molecule, including for determining an association between a polymorphism and a plant trait (49: 5 to 58: 2), for isolating a genetic region (14: 12-13), for determining the level or pattern of protein synthesis in a plant cell (15: 11-23), for determining a mutation in a plant (16: 10-11), and as probes and primers (24: 18 to 25: 2: 46: 15 to 47: 8).

DISCUSSION

Utility under 35 U.S.C. § 101

To fulfill the utility requirement under 35 U.S.C. § 101, a claimed invention must have a specific and substantial utility. *See In re Fisher*, 421 F.3d 1365, 1371, 76 USPQ2d 1225, 1230 (Fed. Cir. 2005). Appellants assert that the utility requirement is satisfied because the claimed nucleic acid molecule can be used to identify the presence or absence of a polymorphism, as a probe, and as a source of primers. Br. 6, 8. The issue before us is whether these utilities are specific and substantial.

Before addressing the specifics of this case, we turn to *Fisher* because that decision involved substantially the same issue and facts presented here. Fisher's claims were to a "substantially purified nucleic acid ... comprising a nucleic acid sequence selected from ... SEQ ID NO: 1 through SEQ ID NO: 5." *Fisher*, 421 F.3d at 1367, 76 USPQ2d at 1227. This is the same claim structure of claim 1 in this appeal. As here, Fisher's claimed nucleic acid was referred to as an EST. The Examiner had rejected Fisher's claims

for lack of utility under 35 U.S.C. § 101, asserting that the disclosed uses were not specific to the claimed ESTs, but generally applicable to any EST. *Id.* The Examiner also asserted that the claimed ESTs lacked a substantial utility. *Id.*

Fisher focused their argument on two utilities: 1) use for the identification of polymorphisms; and 2) use as probes or as a source of primers. *Fisher*, 421 F.3d at 1368, 76 USPQ2d at 1228. These are the same utilities asserted here. Br. 6, 8. Fisher argued that ESTs were comparable to other patentable research tools, such as a microscope. *Fisher*, 421 F.3d at 1373, 76 USPQ2d at 1231. Fisher also contended that ESTs have commercial value. *Fisher*, 421 F.3d at 1377-78, 76 USPQ2d at 1235. In this case, Appellants make these same arguments. Br. 6-7, 11.

The court held that utilities disclosed by Fisher lacked specific and substantial utility because the function of the underlying protein encoded by the claimed nucleic acid molecule had not been identified. *Fisher*, 421 F.3d at 1376, 76 USPQ2d at 1233-34. Accordingly, they concluded that the claims did not satisfy the requirements of 35 U.S.C. § 101.

At issue in this appeal is the same type of claims, for the same utilities considered in *Fisher*. Appellants'[1] arguments also echo those made in *Fisher*. Like Fisher, Appellants have not identified the function of the protein coded for by SEQ ID NO:2. Answer 4. They also have not shown that any polymorphism or nucleic acid identified using SEQ ID NO: 2 as a probe or primer would have a "specific and substantial use." *See Fisher*,

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[1] Monsanto Company is the real party in interest in the instant appeal. Br. 1. Monsanto was also the real party in interest in *Fisher*.

421 F.3d at 1373-74, 76 USPQ2d at 1232. Because of the parallels between the cases, we find that the same reasoning that led the court to reject the utility of Fisher's claims also applies to the instant claims. Accordingly, we affirm the final rejection of claim 1 for lack of utility under § 101 and lack of enablement under §112, first paragraph. Claims 8-13 fall with claim 1.

Written Description under 35 U.S.C. § 112, First Paragraph

The examiner has the initial burden of presenting evidence or reasons why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims. *In re Wertheim*, 541 F.2d 257, 263, 191 USPQ 90, 97 (CCPA 1976). "The 'written description' requirement [under 35 U.S.C. § 112, first paragraph] implements the principle that a patent must describe the technology that is sought to be patented; the requirement serves both to satisfy the inventor's obligation to disclose the technologic knowledge upon which the patent is based, and to demonstrate that the patentee was in possession of the invention that is claimed." *Capon v. Eshhar*, 418 F.3d 1349, 1357, 76 USPQ2d 1078, 1084 (Fed. Cir. 2005).

Claims 1, 8, and 10-13

Appellants have disclosed 91,663 nucleotide sequences identified as SEQ ID NO: 1 through SEQ ID NO: 91663. Specification 11. Each one of these sequences is obtained by sequencing a cDNA molecule isolated from a soybean cDNA library. Specification 104: 20 to 119: 18 (Examples); Br. 18. The invention of claims 1 and 8 is recited to be a "substantially purified nucleic acid molecule" which comprises one of these cDNA sequences, SEQ

ID NO: 2. Thus, Appellants possess what is claimed: a nucleic acid molecule, a cDNA, comprising SEQ ID NO: 2. *See Capon*, 418 F.3d at 1357, 76 USPQ2d at 1084. For this reason, it is our view that the written description requirement is satisfied.

Admittedly, the written description has been applied more restrictively when the claimed subject matter is a DNA. *See, e.g., Fiers v. Revel*, 984 F2d 1164, 25 USPQ2d 1601 (Fed. Cir. 1993); *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). "A cDNA is not defined or described by the mere name 'cDNA,' even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by . . . the recitation of the sequence of nucleotides that make up the cDNA." *Lilly*, 119 F.3d at 1568-69, 43 USPQ2d at 1406. *See also Fiers*, 984 F.2d at 1170-71, 25 USPQ2d at 1606-07. Thus, the written description of a nucleic acid molecule is satisfied by the disclosure of its nucleotide sequence. Here, the specification discloses a definite and precise nucleotide sequence of the claimed nucleic acid molecule: SEQ ID NO:2. Accordingly, we find that the disclosure of SEQ ID NO:2 is sufficient to satisfy the written description requirement for claims 1 and 8 even under the more rigid standard.

The Examiner argues that the claims lack written description because SEQ ID NO: 2 is not a complete gene. Answer 6.

> [T]he claims embrace full length mRNAs, cDNAs and genomic sequences, and the specification provides no physical (i.e. structural) characteristics of these molecules to distinguish them from other nucleic acid molecules comprising the claimed SEQ ID NO. 2, and no other indication that would suggest Appellant possessed them.

Supp. Answer 2.

Contrary to the Examiner's argument, Appellants have described a physical characteristic and feature of the claimed invention that distinguishes it from other nucleic acid molecules: SEQ ID NO:2, a defined and ordered nucleotide sequence. Full-length mRNAs, complete cDNAs, and genomic sequences which contain SEQ ID NO:2 would each be characterized by this definite sequence. We can find no language in the claim that would require a description of non-coding and regulatory sequences as demanded by the Examiner. Answer 6. The Examiner appears to have read limitations into the claim which are not there.

To determine compliance with the written description requirement, it is necessary that the patent disclosure be sufficiently detailed to enable a person of skill in the art to recognize that applicants have invented what is claimed. *LizardTech Inc. v. Earth Resource Mapping Inc.*, 424 F.3d 1336, 1344, 76 USPQ2d 1724, 1732 (Fed. Cir. 2005). Here, Appellants have invented SEQ ID NO:2 and claim molecules which comprise it. We do not see how possession of the claimed nucleic acid molecule is lost by appending other sequences to SEQ ID NO:2.

Claim 1 also recites that the nucleic acid molecule "encodes a soybean protein or fragment thereof." The Examiner asserts that the claim lacks written description because the specification does not identify its open reading frame or the protein which it encodes. Answer 3-4.

The purpose of the written description requirement is to establish possession of the claimed invention. The touchstone of possession for a nucleic acid molecule is its nucleotide sequence. *Lilly*, 119 F.3d at 1568-69,

43 USPQ2d at 1406. *See also Fiers*, 984 F.2d at 1170-71, 25 USPQ2d at 1606-07. In this case, what is claimed is a nucleic acid molecule which comprises the nucleotide sequence of SEQ ID NO: 2. The recitation in the claim that molecule encodes "a soybean protein or fragment thereof" is merely a statement of a function, or inherent property, which is a consequence of it being isolated from a cDNA library. Br. 18. Consequently, it is not necessary in this case for the specification to describe the protein or its open reading frame to comply with the written description requirement.

Claims 10-13

Claims 10-13 are drawn to nucleic acid molecules having 90% to 100% sequence identity to SEQ ID NO:2. The Examiner further considers these claims unpatentable because the specification does not disclose "what is the necessary common attribute for the polynucleotides encompassed by the claimed genus to encode proteins belonging to the same species."[2] Supp. Answer 2. *See also* Answer 8.

Under *Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406, a written description of a genus can be satisfied by describing a structural feature "commonly possessed" by its members. In this case, the requirement in claim 10 that the claimed molecule comprise "between 100% and 90% sequence identity with a nucleic acid sequence of SEQ ID NO: 2" is a structural feature "commonly possessed" by members of the claimed genus.

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[2] The Examiner's statement is incorrect. The claims do not require the genus members "to encode proteins belonging to the same species." Supp. Answer 2.

Members of this genus can be determined using known alignment algorithms. Specification 5: 20 to 6: 20. Accordingly, we find the written description requirement to be satisfied for claims 10-13.

In summary, we find claims 1, 8, and 10-13 to be in compliance with the written description requirement. The rejection is reversed.

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

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